

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

EPITOPIX, LLC
d/b/a VAXXINOVA US,

Plaintiff,

v.

ZOETIS INC.,

Defendant.

Case No. 2:23-cv-02467 (BRM) (JSA)

OPINION

MARTINOTTI, DISTRICT JUDGE

Before this Court are the applications by Plaintiff Epitopix, LLC d/b/a Vaxxinova US (“Vaxxinova”) and Defendant Zoetis Inc. (“Zoetis”) for claim construction to resolve disputes over several claim terms. (ECF Nos. 48, 49, 62, 64.)

This Court has examined the disputes over the construction of these claim terms and, for the reasons set forth in this Opinion, this Court defines the disputed claim terms as follows:

- (1) “expressed by the [a] gram negative microbe when the gram negative microbe is grown in the presence of [24 µg/mL] 2,2-dipyridyl” means “expressed by the [a] gram-negative microbe when the gram negative microbe is grown in the presence of [24 µg/mL] 2,2- dipyridyl”;
- (2) “wherein at least one SRP is not expressed by the gram negative microbe at a detectable level when the gram negative microbe is grown in the absence of 2,2-dipyridyl” means “at least one of the at least two SRPs is characterized by being an SRP that is not present at a detectable level if the gram- negative microbe is grown in the absence of 2,2- dipyridyl”;

- (3) “an SRP that is not expressed when the gram negative microbe is grown in the absence of 24 µg/mL 2,2-dipyridyl” means “an SRP is characterized by being an SRP that is not present at a detectable level if the gram- negative microbe is grown in the absence of 24 µg/mL 2,2- dipyridyl”;
- (4) “[at least two/a plurality of] [siderophore receptor polypeptides (SRPs)/porins]” has its plain and ordinary meaning;
- (5) “a composition comprising: an isolated whole cell preparation [of gram negative microbes]” means “a composition comprising whole microbial cells where the whole cells have been either removed from their natural environment, produced using recombinant techniques, or chemically or enzymatically synthesized”; and
- (6) “detectable level” has its plain and ordinary meaning.

Finally, the Court defers its decision on the “wherein the gram negative microbe comprises an *E. coli* mutant lacking outer oligosaccharide side chains of LPS” claim term until a more complete record is developed.

I. BACKGROUND

A. Factual Background

This case arises out of an action for patent infringement instituted by Vaxxinova against Zoetis, related to U.S. Patent No. 8,637,048 (filed Jan. 19, 2001) (the “’048 Patent”). (ECF No. 1 (Complaint) ¶ 1.) Vaxxinova is incorporated in Minnesota and is a wholly owned subsidiary of a Dutch company, Vaxxinova International BV. (*Id.* ¶ 2.) Zoetis is incorporated in Delaware, with its principal place of business in New Jersey. (*Id.* ¶ 3.) Both parties engage in the research and development of products related to animal health in the agricultural context, including the discovery and development of vaccines. (*Id.* ¶¶ 7–9.)

The '048 Patent was issued by the U.S. Patent and Trademark Office on January 28, 2014; Vaxxinova is the owner by assignment. (*Id.* ¶ 15.) The '048 Patent is one of a family of related patents by Vaxxinova concerning siderophore receptor protein (“SRP”) vaccines targeted to bacterial infections common in livestock, such as *E. coli* and *salmonella*. (*Id.* ¶¶ 8, 10–14.) SRPs are an example of a class of proteins called porins, “which transport nutrients through the bacterial cell wall.” (*Id.* ¶ 10.) Bacteria need iron to grow and survive, and they deploy SRPs to capture iron within the host animal, where iron is typically available in low quantities. (*Id.*; ECF No. 88 (*Markman* Tr.) at 12:23–25.) Many species of bacteria share identical SRPs, meaning an effective SRP vaccine can combat multiple types of disease-causing bacteria. (ECF No. 1 ¶ 11.) An effective SRP vaccine prompts the inoculated animal to generate antibodies that target bacteria presenting the SRPs in the vaccine. (*Id.* ¶ 12.)

The '048 Patent also describes lipopolysaccharides (“LPS”), a type of endotoxin present on the cell membrane of bacteria. (*Id.* ¶ 13.) LPS form oligosaccharide side chains of LPS (“O-chains of LPS”) on the surface of bacteria of variable lengths. (ECF No. 88 at 31:19–32:04.) The presence of LPS in a vaccine can cause inflammation and scarring at the vaccine injection site—both undesirable outcomes in meat production. *See* '048 Pat. at col. 1 ll. 42–57. The '048 Patent therefore seeks to describe an SRP vaccine composition with low amounts of LPS. *See id.* at col. 2 ll. 6–8. (ECF No. 1 ¶ 13.) The parties seek construction of several related groups of terms, listed below, though Vaxxinova argues several terms Zoetis would have the Court construe need only plain and ordinary meaning, while Zoetis contends several terms are indefinite:

Claim Language	Asserted Claims	Plaintiff's Proposed Construction	Defendant's Proposed Construction
“expressed by the [a] gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl”	Claim 4; Claim 14	“The SRPs are of a class of siderophore receptor polypeptides that are expressed when the Gram-negative bacteria are grown under conditions of iron restriction, such as in the presence of 2,2'-dipyridyl or a similar iron chelating agent.”	“The [‘at least two’/‘plurality of’] SRPs are characterized by being SRPs that are only expressed by the [a] gram-negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl.”
“[expressed by the gram negative microbe] when the gram negative microbe is grown in the presence of 24 µg/mL 2,2-dipyridyl”	Claim 5; Claim 15	“[The SRPs are of a class of siderophore receptor polypeptides that are expressed] when the Gram-negative bacteria are grown under conditions of iron restriction, such as in the presence of 2,2'-dipyridyl or a similar iron chelating agent.”	“The [‘at least two’/‘plurality of’] SRPs are characterized by being SRPs that are only expressed by the gram-negative microbe when the gram-negative microbe is grown in the presence of 24 µg/mL 2,2-dipyridyl.”
“wherein at least one SRP is not expressed by the gram negative microbe at a detectable level when the gram negative microbe is grown in the absence of 2,2-dipyridyl”	Claim 6; Claim 16	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “one or more of the SRPs are of a class of siderophore receptor polypeptides that are not expressed at a detectable level when the bacteria are grown without an iron chelating agent, such as 2,2'- dipyridyl.”	“At least one of the at least two SRPs is characterized by being an SRP that is not present at a detectable level if the gram- negative microbe is grown in the absence of 2,2-dipyridyl.”
“an SRP that is not expressed when the	Claim 7; Claim 17	Plain and ordinary meaning.	“An SRP is characterized by

gram negative microbe is grown in the absence of 24 µg/mL 2,2-dipyridyl”		If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “at least one SRP is not expressed at a detectable level under the stated conditions when the bacteria is grown without an iron chelating agent, such as 2,2'-dipyridyl.”	being an SRP that is not present at a detectable level if the gram- negative microbe is grown in the absence of 24 µg/mL 2,2-dipyridyl.”
“wherein the gram negative microbe comprises an <i>E. coli</i> mutant lacking outer oligosaccharide side chains of LPS”	Claim 21; Claim 22	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “the gram-negative microbe includes a mutant or modified strain of <i>E. coli</i> bacteria having lipopolysaccharides that lack outer oligosaccharide side chains.”	The term is indefinite and is not reasonably amenable to a construction at least because the bounds of this term cannot be defined.
“at least two siderophore receptor polypeptides (SRPs)”	Claim 4; Claim 6; Claim 21	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “two or more types of siderophore receptor polypeptides.”	The term is indefinite and not amenable to construction. Whether “at least two” refers to two molecules, or two different kinds, of siderophore receptor polypeptide is indefinite and no definition finds support in the patent claims, specification, or prosecution history.
“at least two porins”	Claim 4; Claim 6; Claim 21	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “two or more types of porin polypeptides” While porins	The term is indefinite and not reasonably susceptible to a definition. Whether this limitation requires at least two porin molecules or

		are understood by persons of ordinary skill in the art and do not need any construction, to the extent any construction is deemed necessary, porins are transmembranous pore-forming proteins in the outer membrane of Gram-negative bacteria through which small molecules can diffuse.	two types of porin is undefined.
“a plurality of siderophore receptor polypeptides (SRPs)”	Claim 14; Claim 16; Claim 22	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “two or more types of siderophore receptor polypeptides.”	The claim term is indefinite and not reasonably amenable to definition. The plain meaning of plurality is two or more. However, whether “a plurality” refers to two or more molecules, or two or more different kinds, of siderophore receptor polypeptide is undefined.
“a plurality of porins expressed by the [a] gram negative microbe”	Claim 14; Claim 16; Claim 22	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “two or more types of porin proteins expressed by the respective Gram- negative bacteria under the stated conditions.”	The claim term is indefinite and not reasonably amenable to definition. The plain meaning of plurality is two or more. However, whether “a plurality” refers to two or more molecules, or two or more different kinds, of siderophore receptor polypeptide is undefined.
“A composition comprising: an isolated whole cell preparation [of gram negative microbes]”	Claim 4; Claim 6; Claim 21	Plain and ordinary meaning. The preamble, “a composition comprising,” is not limiting and need not be construed.	“A composition comprising whole microbial cells where the whole cells have been removed from

		If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “a composition containing, but not limited to, whole cells or cell debris isolated from a Gram-negative bacteria.”	their natural environment.”
“Detectable level”	Claim 6; Claim 7; Claim 16; Claim 17	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “the amount of a protein that can be identified using a given assay (e.g., polyacrylamide gel analysis using conventional Coomassie staining, western immunoblotting analysis using primary antibodies capable of binding to the protein of interest, [or mass spectrometry technologies] ¹).”	This term is indefinite and cannot reasonably be construed.

B. Procedural History

On May 4, 2023, Vaxxinova filed a Complaint asserting claims of infringement against Zoetis. (ECF No. 1.) On July 7, 2023, Zoetis filed an Answer to the Complaint along with counterclaims asserting the noninfringement and invalidity of the patent-in-suit. (ECF No. 22.) Vaxxinova filed its own Answer to Zoetis’s counterclaims on July 28, 2023. (ECF No. 25.)

On April 23, 2024, Vaxxinova and Zoetis filed their opening *Markman* briefs. (ECF Nos. 48, 49.) On June 17, 2024, both parties filed their *Markman* reply briefs. (ECF Nos. 62, 64.) The Court held a *Markman* Hearing on October 30, 2024. (ECF No. 81.) Based on the parties’

¹ The bracketed language is included in Vaxxinova’s proposed construction in Exhibit A of the prehearing statement (ECF No. 45), but it is not included in Vaxxinova’s briefings.

presentations, the Court determined supplemental briefing was warranted. (ECF No. 82.) Pursuant to the Court’s request, Vaxxinova and Zoetis each filed supplemental briefing on November 27, 2024. (ECF Nos. 85, 86.)

II. LEGAL STANDARD

Claims define the scope of the inventor’s right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope and is a determination reserved exclusively for the court as a matter of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996). Indeed, the court can only interpret claims and “can neither broaden nor narrow claims to give the patentee something different than what it has set forth” in the specification. *E.I. Du Pont de Nemours v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1998). A court’s determination “of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art (“POSA”). *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman*, 52 F.3d at 986 (holding that “[t]he focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean”); *Phillips*, 415 F.3d at 1312–13. In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification, and the prosecution history) and extrinsic evidence (e.g., expert reports and testimony). *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).

The analysis of claim language begins with determining the “ordinary and customary meaning of a claim term[, which] is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313. Further, the language should not be read solely in the context of the claim under review; instead, it should be analyzed “in the context of the entire patent” and with an understanding of how that language is used in the field from which the patent comes. *Id.* In conducting this review, a different interpretation is placed on a term located in an independent claim than on those located in dependent claims, and it is understood that each claim covers different subject matter. *See Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1331 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1315 (holding that the “presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim”)).

In reviewing the language of a patent, “the court starts the decision-making process by reviewing the same resources as would [a person of ordinary skill in the art in question], *viz.*, the patent specifications and the prosecution history.” *Phillips*, 415 F.3d at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). When “the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent,” understanding claim construction “involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314. “In such circumstances, general purpose dictionaries may be helpful” to explain the terms used. *Id.*

Often, however, the ordinary meaning of the claim language is not readily apparent, and in such circumstances, courts look to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Id.* Those sources may

include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* Furthermore, claims must be read in view of the claim specification, which is of seminal importance in providing framework for understanding the claim language. As the Federal Circuit explained:

The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. As we have often stated, a patentee is free to be his [or her] own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification. The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.

Markman, 52 F.3d at 979–80 (internal citations omitted).

This Court’s reliance on the specification is appropriate given the Patent and Trademark Office’s rules requiring “application claims . . . ‘conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent bases in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.’” *Phillips*, 415 F.3d at 1316–17 (quoting 37 C.F.R. § 1.75(d)(1)). During this analysis, however, courts should not “import limitations from the specifications into the claims.” *Innogenetics, N.V. v. Abbott Lab’ys*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quoting *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005)).

The patent’s prosecution history is also of “primary significance in understanding the claims.” *Markman*, 52 F.3d at 980. “The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than

it would otherwise be.” *Phillips*, 415 F.3d at 1317. Further, the prosecution history is also relevant to determining whether the patentee disclaimed or disavowed the subject matter, thereby narrowing the scope of the claim terms. *Seachange Int’l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372–73 (Fed. Cir. 2005).²

In addition to intrinsic evidence, a court may also rely on extrinsic evidence in interpreting a claim. *Phillips*, 415 F.3d at 1317. Extrinsic evidence consists of “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Id.* (citations omitted). However, while extrinsic evidence “can shed useful light on the relevant art,” it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* Extrinsic evidence should be “considered in the context of intrinsic evidence,” as there are flaws inherent in the exclusive reliance on extrinsic evidence, including, *inter alia*, biases, inadvertent alterations of meanings, and erroneous contextual

² “[I]n certain cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor.” *Ventana Med. Sys., Inc. v. Biogenex Lab’ys, Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) (quoting *Phillips*, 415 F.3d at 1316) (internal citations omitted). In such cases, the Federal Circuit interprets the claim more narrowly than it otherwise would in order to give effect to the patentee’s intent to disavow a broader claim scope. *Id.* (citing *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319–20 (Fed. Cir. 2006); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342–44 (Fed. Cir. 2001)). However, pointing solely to “general statements by the [patentee] indicating that the invention is intended to improve upon prior art” will not demonstrate that the patentee intended to “disclaim every feature of every prior art device discussed in the ‘BACKGROUND ART’ section of the patent.” *Id.*; see also *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (“Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.”). Moreover, the Federal Circuit has found it “particularly important not to limit claim scope based on statements made during prosecution ‘[a]bsent a clear disavowal or contrary definition.’” *Digit. Vending Servs. Int’l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1273 (Fed. Cir. 2012) (citing *Aug. Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1286 (Fed. Cir. 2011)). The reason for such a stringent rule is “because the prosecution history represents an ongoing negotiation between the PTO and the application,” and “it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Digit. Vending*, 672 F.3d at 1273 (quoting *Phillips*, 415 F.3d at 1317).

translations. *Id.* at 1318–19. Furthermore, extrinsic evidence should not be relied upon where “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

III. DECISION

This Court addresses the interpretation of the disputed terms below, grouped by their shared characteristics as applicable.

A. The Meaning of “[expressed] when the gram negative microbe is grown in the [presence/absence] of [24 µg/mL] 2,2-dipyridyl.”

Claim Language	Asserted Claims	Plaintiff's Proposed Construction	Defendant's Proposed Construction
“expressed by the [a] gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl”	Claim 4; Claim 14	“The SRPs are of a class of siderophore receptor polypeptides that are expressed when the Gram-negative bacteria are grown under conditions of iron restriction, such as in the presence of 2,2'-dipyridyl or a similar iron chelating agent.”	“The [‘at least two’/‘plurality of’] SRPs are characterized by being SRPs that are only expressed by the [a] gram-negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl.”
“[expressed by the gram negative microbe] when the gram negative microbe is grown in the presence of 24 µg/mL 2,2-dipyridyl”	Claim 5; Claim 15	“[The SRPs are of a class of siderophore receptor polypeptides that are expressed] when the Gram-negative bacteria are grown under conditions of iron restriction, such as in the presence of 2,2'-dipyridyl or a similar iron chelating agent.”	“The [‘at least two’/‘plurality of’] SRPs are characterized by being SRPs that are only expressed by the gram-negative microbe when the gram-negative microbe is grown in the presence of 24 µg/mL 2,2-dipyridyl.”

“wherein at least one SRP is not expressed by the gram negative microbe at a detectable level when the gram negative microbe is grown in the absence of 2,2-dipyridyl”	Claim 6; Claim 16	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “one or more of the SRPs are of a class of siderophore receptor polypeptides that are not expressed at a detectable level when the bacteria are grown without an iron chelating agent, such as 2,2'-dipyridyl.”	“At least one of the at least two SRPs is characterized by being an SRP that is not present at a detectable level if the gram- negative microbe is grown in the absence of 2,2-dipyridyl.”
“an SRP that is not expressed when the gram negative microbe is grown in the absence of 24 µg/mL 2,2-dipyridyl”	Claim 7; Claim 17	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “at least one SRP is not expressed at a detectable level under the stated conditions when the bacteria is grown without an iron chelating agent, such as 2,2'-dipyridyl.”	“An SRP is characterized by being an SRP that is not present at a detectable level if the gram- negative microbe is grown in the absence of 24 µg/mL 2,2-dipyridyl.”

Claims 4–7 and 14–17 of the '048 Patent describe compositions of SRPs expressed by gram-negative bacteria in the presence or absence of “2,2-dipyridyl.” Claims 5, 7, 15, and 17 specify a concentration of 2,2-dipyridyl, 24 µg/mL. (ECF No. 48 at 5.)

1. Claim Construction

The parties agree 2,2-dipyridyl is an iron-chelating agent, meaning it can reduce the amount of iron in the growth media for the bacteria (also known as a “chelator”). (ECF No. 48 at 19; ECF No. 49 at 23.) Vaxxinova contends, however, a POSA would understand the use of “2,2-dipyridyl” in these claims as characterizing a test condition to identify the presence of the SRPs sought for the vaccine, for which any iron chelator could be used. (ECF No. 49 at 22.) Zoetis disagrees and argues the specific use of “2,2-dipyridyl” means the composition described by these terms must contain SRPs *only* expressed by bacteria in the presence of 2,2-dipyridyl, but not in the presence of any other iron chelator. (ECF No. 48 at 7.) Because there are no known SRPs expressed only in the presence of 2,2-dipyridyl but no other iron chelators, Zoetis also argues these claims are indefinite and therefore invalid. (*Id.* at 5–6 (citing *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004)).)

Vaxxinova argues the claims describing SRPs expressed in the presence or absence of 2,2-dipyridyl serve to indicate “what classes of SRPs are encompassed within the claimed composition.” (ECF No. 48 at 23.) Vaxxinova asserts the claim language would tell a POSA the SRPs at issue will be expressed in the presence of 2,2-dipyridyl or other iron-chelating agents, and that any iron chelator could be substituted for 2,2-dipyridyl to achieve the same result. (*Id.* at 23–24.) This reading is supported by Vaxxinova’s expert, Dr. James Galen (*id.* at 24), who says “there is no such thing” as an SRP expressed only in the presence of 2,2-dipyridyl, and a POSA “would understand that other iron chelators may be substituted for 2,2’-dipyridyl and have the same result” (ECF No. 45-2, Ex. B (James Galen Declaration) ¶ 9). In other words, Vaxxinova contends this language describes a test condition the inventors used to create the composition and cites to case law indicating it is improper to read a test condition or method step “as an affirmative claim limitation.” (ECF No. 49 at 22 (citing *Ex Parte Hough & Feshazion*, No. 2009-002932, 2009 Pat.

App. LEXIS 6116, *10–14 (B.P.A.I. July 22, 2009); *IPXL Holdings, LLC v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005).) And Vaxxinova argues Zoetis’s construction requires an impossibility that renders the claim indefinite, which the Federal Circuit disfavors. (ECF No. 64 at 10–11 (citing *AlterWAN, Inc. v. Amazon.com, Inc.*, 63 F.4th 18, 23 (Fed. Cir. 2023))).) In its reply brief, Vaxxinova also asserts that, had the patentees meant to refer to SRPs only expressed in the presence of 2,2-dipyridyl, excluding all other iron chelators, they would have written “SRPs expressed *from* a gram negative microbe grown in the presence of 2,2-dipyridyl.” (*Id.* at 10.) In contrast, Vaxxinova argues the words used (“SRPs *expressed when* the gram negative microbe *is grown . . .*”) define a class of SRPs by a characteristic identifiable by growing bacteria in the presence of any iron chelator. (*Id.*) Additionally, Vaxxinova contends Zoetis’s interpretation imports the preferred embodiment of an iron chelator—2,2-dipyridyl—into the claims as a limitation, against a common canon of patent construction. (*Id.* at 12 (citing *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1343 (Fed. Cir. 2001); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988)); ECF No. 86 at 12–13 (citing *NovaPlast Corp. v. Inplant, LLC*, No. 20-7396, 2023 U.S. Dist. LEXIS 128873, at *16 (D.N.J. July 26, 2023); *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1357 (Fed. Cir. 2004); *Phillips*, 415 F.3d at 1323).)

For its part, Zoetis asks the Court to construe the language of the claims containing “grown in the [presence/absence] of [24 µg/mL] 2,2-dipyridyl” exactly as written because interpreting the language as Vaxxinova proposes would improperly write an express requirement out of the claims, contrary to their plain meaning. (ECF No. 48 at 7–8.) While Zoetis agrees with Vaxxinova and Dr. Galen that an SRP expressed only in the presence of 2,2-dipyridyl (and not other iron chelators) is scientifically impossible, Zoetis argues this is an admission by Vaxxinova that this language cannot be construed to cover all conditions of iron restriction. (*Id.* at 7.) Zoetis supports this

argument by highlighting structural aspects of the relevant claims. (*Id.* at 9–17.) Zoetis compares claims 4 and 14 (which describe a composition comprising SRPs “expressed by a gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl”) with claims 6 and 16 (which describe a composition where “one SRP is not expressed by the gram negative microbe at a detectable level when the gram negative microbe is grown in the absence of 2,2-dipyridyl”) to conclude “the SRPs of Claims 4 and 14 must be SRPs that are only expressed by gram negative bacteria in the presence of 2,2-dipyridyl and are not SRPs that are expressed in the absence of 2,2-dipyridyl,” in line with the canon to construe claims consistently within the patent. (*Id.* at 9–10.) Zoetis also points to claims 5 and 15 and 7 and 17, which follow the language of claims 4 and 14 and 6 and 16, respectively, but add a specific concentration of 2,2-dipyridyl, 24 µg/mL. (*Id.* at 5.) Zoetis argues Vaxxinova’s proposed construction would impermissibly write the specific concentrations out of the claims, making them identical to claims 4 and 14 and claims 6 and 16 and violating the principle of claim differentiation. (*Id.* at 11–13 (citing *Brassica Prot. Prods. LLC v. Sunrise Farms (In re Cruciferous Sprout Litig.)*, 301 F.3d 1343, 1349 (Fed. Cir. 2002)), 15–17.) Zoetis also contends the ’048 Patent specification’s references to “low iron conditions,” preferably created by the presence of an iron chelator, are insufficient to define “2,2-dipyridyl” as any iron chelator or “conditions of iron restriction.” (*Id.* at 10–11.)

Analysis of claim language begins with determining the “ordinary and customary meaning of a claim term” to a POSA, “in the context of the entire patent.” *Phillips*, 415 F.3d at 1313. When claim language is ambiguous on its face, a court can consult other intrinsic evidence, including the patent’s prosecution history. *Id.* at 1314; *see also Markman*, 52 F.3d at 980. The prosecution history is also relevant to determining whether the patentee disclaimed or disavowed the subject matter, thereby narrowing the scope of the claim. *Seachange Int’l*, 413 F.3d at 1372–73.

The '048 Patent does not define "2,2-dipyridyl." But the intrinsic evidence, though not definitive, tilts in favor of Zoetis's proposed construction. The '048 Patent's specifications teach that, "in some aspects of the invention, SRPs are expressed by a microbe at high levels when the microbe is exposed to low iron conditions," '048 Pat. at col. 5 ll. 29–31, preferably as the result of "the addition of an iron chelating compound to [the] media," and discuss several iron chelators, including 2,2-dipyridyl, *id.* at col. 11 ll. 50–59. But these excerpts from the specification do not clearly indicate 2,2-dipyridyl would be understood by a POSA as a stand-in for all iron chelators. And, as Zoetis points out, claims 5, 7, 15, and 17 recite a specific concentration of 2,2-dipyridyl, 24 µg/mL, indicating the level of 2,2-dipyridyl is relevant to understanding their different scope as compared to claims 4, 6, 14, and 16, which use the same language without a specific concentration. If read as Vaxxinova suggests, the language in claims 4 and 14 would describe the same general conditions of iron restriction as those in 5 and 15, and claims 6 and 16 would similarly describe the same conditions as those in 7 and 17. *See In re Cruciferous Sprout Litig.*, 301 F.3d at 1348–49 (finding party's proposed construction would render dependent claim adding a specific quantity of the product to be produced superfluous); *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 690 F.3d 1318, 1324–25 (Fed. Cir. 2012) ("[T]he presumption [of claim differentiation] is 'especially strong' in this case, because 'the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.''" (citing *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003))).

Vaxxinova argues Zoetis's interpretation limits these claims to a preferred embodiment, but this argument seemingly asks this Court to apply this canon of construction in reverse. Cases describing the canon against reading preferred embodiments as limitations, including those

Vaxxinova cites (ECF No. 49 at 23–24; ECF No. 64 at 12; ECF No. 86 at 12–13), typically prevent preferred embodiments in *specifications* from limiting broader terms in *claims*. See *Gart*, 254 F.3d at 1343 (“[I]t is well established that *broad claims* supported by the written description should not be limited in their interpretation to a preferred embodiment.” (emphasis added)); *Laitram Corp.*, 863 F.2d at 865 (“References to a preferred embodiment, such as *those often present in a specification*, are not claim limitations.” (emphasis added)); *NovaPlast*, 2023 U.S. Dist. LEXIS at *17–20 (refusing to limit claim construction to embodiment described in specification and prosecution history, “a plurality of fasteners” (i.e., more than one), when plain meaning of the term at issue, “at least one . . . fastener” (i.e., one or more), encompassed more options); *Home Diagnostics, Inc.*, 381 F.3d at 1357 (“The preferred embodiments that used the predetermined timing method simply do not limit the *broader claim language*.” (emphasis added)); *see also Advanced Card Techs., LLC v. Versatile Card Tech., Inc.*, 410 F. Supp. 2d 158, 167 (S.D.N.Y. 2006) (“[I]t is well settled that the invention is not limited to the preferred embodiment *if the claim language is broader than that single embodiment*.” (emphasis added)). But here, what Vaxxinova characterizes as the preferred embodiment (2,2-dipyridyl) is written into the claim, and the specification lists a broader array of iron chelators. The case law cited provides no support for employing this canon in this manner. Indeed, the rationale behind this canon is to allow the patentee “to provide [a POSA with] an example of how to practice the invention in a particular case” in the specification without penalizing the patentee, as POSAs “rarely would confine their definitions of terms to the exact representations *depicted in the embodiments*.” *Phillips*, 415 F.3d at 1323 (emphasis added). The Federal Circuit has also explained that, when a patent makes clear the embodiment described is the invention itself, the principle against reading embodiments as limitations does not apply. See, e.g., *Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1321–22

(Fed. Cir. 2011) (limiting term where specification explicitly defined the invention throughout by using phrase “the instant invention”). At the very least, this canon does not resolve the ambiguous nature of these claim terms.

At oral argument, Zoetis (for the first time) asserted that Vaxxinova had disclaimed chelators other than 2,2-dipyridyl through amendments based on the patent examiner’s rejection of certain claims due to prior art. (ECF No. 88 at 82:01–87:13.) In that presentation and supplementary briefing requested by the Court, Zoetis contends the patent applicants modified several application claims that originally described SRPs expressed “when the gram negative microbe is grown in the presence of a metal chelator” to instead say “grown in the presence of 2,2-dipyridyl,” the language of claim terms at issue.³ (ECF No. 79-1 (Ex. U, Prosecution History of ’048 Patent) at VAXX_000330–32.) This revision followed the patent examiner’s rejection over a prior patent application by the same inventor-applicants, Emery WO 95/21627 (“Emery”), which the examiner believed “disclose[d] the use of metal chelators such as 2,2-dipyridyl,” as well as isolated SRPs in a “physiologically acceptable carrier.” (ECF No. 85 at 9–10 (quoting ECF 79-1,

³ The application claims referencing “a metal chelator” were a series of dependent claims stemming from application claim 72 (“A composition comprising an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise: at least two siderophore receptor polypeptides (SRPs); at least two porins; and a pharmaceutically acceptable carrier”). (ECF No. 79-1 at VAXX_000330.) Application claim 81 disclosed: “The composition of claim 72 wherein the SRPs comprise SRPs expressed by the gram negative microbe when the gram negative microbe is grown in the presence of a metal chelator,” and application claim 82 disclosed: “The composition of claim 81 wherein the metal chelator comprises 2,2-dipyridyl.” (*Id.* at VAXX_000331.) Application claim 84 similarly disclosed: “The composition of claim 81 wherein the SRPs comprise at least one SRP that is not expressed by the gram negative microbe at a detectable level when the gram negative microbe is grown in the absence of a metal chelator,” and application claim 85 depended on 84 but added “wherein the metal chelator comprises 2,2-dipyridyl.” (*Id.* at VAXX_000332.) A similar pattern follows for application claims 90, 99, 100, 102, and 103. (*Id.* at VAXX_000332–34.) Application claims 82 and 85 correspond to claims 4 and 6 in the ’048 Patent, and application claims 100 and 103 correspond to claims 14 and 16. (ECF No. 84 at 9.)

VAXX_000293).) In Zoetis's reading of the prosecution history, the examiner repeatedly rejected the applicants' attempts to distinguish the claims from Emery, including by arguing Emery taught only a cell culture medium containing "the chelators named in the specification, 2,2-dipyridyl and deferoxamine," both of which were deleterious to health and not pharmaceutically acceptable. (*Id.* at 10–11.) Following a third rejection on the same grounds, the applicants made significant amendments to the claims. (*Id.* at 11.) Using application claim 82 as an exemplar, Zoetis explains it was rewritten to incorporate elements of application claims 72 and 81, removing all reference to a "metal chelator" and replacing it with "grown in the presence of 2,2-dipyridyl." (*Id.* at 12.)

82. (Currently Amended) A composition comprising:
an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise:
at least two siderophore receptor polypeptides (SRPs) expressed by the gram negative microbe when the gram negative microbe is grown in the presence of The composition of claim 81 wherein the metal chelator comprises 2,2-dipyridyl; and
at least two porins; and
a pharmaceutically acceptable carrier.

(ECF No. 79-1 at VAXX_000136.) Zoetis contends the applicants' substitution of "grown in the presence of 2,2-dipyridyl" in place of the more general "metal chelator" term, in response to the examiner's repeated rejections, constitutes "clear disavowal" of Vaxxinova's proposed construction, as metal chelators would encompass iron chelators. (ECF No. 85 at 12–13 (citing *United Video Props., Inc. v. Amazon.com, Inc.*, 561 F. App'x 914, 918 (Fed. Cir. 2014))).) Zoetis also asserts the Court must consider this argument, despite its belated appearance, because prosecution history is a key element of intrinsic evidence of which the Court may take judicial notice, even if not presented by the parties. (*Id.* at 4–5.) Zoetis contends Vaxxinova "opened the door" to this argument by presenting an alternative drafting of the claims at issue to argue against Zoetis's proposed construction. (*Id.* at 6–7.)

Vaxxinova calls Zoetis's prosecution history argument untimely and asks the Court not to consider it. (ECF No. 86 at 2–5.) Pointing to this District's Local Patent Rules, Vaxxinova argues Zoetis failed to surface this prosecution history argument during the exchange of preliminary claim constructions, supporting evidence, and responsive evidence pursuant to L. Pat. R. 4.2(a)–(c), or in the parties' joint claim construction statement required by L. Pat. R. 4.3, making Zoetis's presentation at oral argument an improper amendment to those papers. (*Id.* at 3.) Vaxxinova supports this argument with citations to opinions wherein it contends courts in this District have rejected belated arguments based on a patent's prosecution history, most involving requests to amend a party's invalidity contentions. (*Id.* at 3–5.) Vaxxinova also asserts it never changed its claim construction arguments, so Zoetis's new prosecution history argument does not meet the good cause requirement for amendment under the Local Patent Rules. (*Id.* at 5–6.)

While Zoetis's prosecution history argument was certainly late-coming, the Court will consider it. A patent's prosecution history "constitutes a public record of the patentee's representations concerning the scope and meaning of the claims." *Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l*, 222 F.3d 951, 957 (Fed. Cir. 2000). As such, it is "subject to judicial notice," and arguments stemming from it are not so easily waived. *Uniloc USA, Inc. v. ADP, LLC*, 772 F. App'x 890, 898 n.3 (Fed. Cir. 2019) (taking judicial notice of patent prosecution history where party raised it as support on appeal for argument presented to district court); *see also Group14 Techs., Inc. v. Nexeon Ltd.*, 2024 U.S. Dist. LEXIS 168547, at *6 n.5 (W.D. Wash. Sept. 18, 2024) (taking judicial notice of prosecution history documents not provided by party at summary judgment); *Horizon Meds. LLC v. Dr. Reddy's Lab'ys, Inc.*, 2019 U.S. Dist. LEXIS 218330, at *15 n.3 (D.N.J. Dec. 18, 2019) (taking judicial notice of prosecution history not included as exhibit). This Court has also identified instances where courts have considered new supporting arguments for a claim

construction at a *Markman* hearing for terms a court had already been asked to construe. *See Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1381 (Fed. Cir. 2002) (“Appellee argues that appellants significantly altered the scope of their claim construction on appeal. However, the argument raised during oral argument simply provided additional support for appellants' previously argued claim construction.”) (considering prosecution history argument made only on appeal); *Sun Microsystems, Inc. v. Network Appliance, Inc.*, 710 F. Supp. 2d 925, 956 (N.D. Cal. 2008) (considering new argument for prosecution disclaimer raised at oral argument); *Fujitsu Ltd. v. Belkin Int'l, Inc.*, 2012 U.S. Dist. LEXIS 13490, at *20–21 (N.D. Cal. Feb. 3, 2012) (considering new arguments based on prior art raised at oral argument); *Indus. Tech. Rsch. Inst. v. LG Elecs.*, 2014 U.S. Dist. LEXIS 1557, at *71–72 n.24 (D.N.J. Jan. 6, 2014) (considering new arguments presented during *Markman* hearing because “the Court has endeavored to provide the parties with a full and fair opportunity to present their arguments”); *accord Transonic Sys. v. Non-Invasive Med. Techs. Corp.*, 75 Fed. App'x 765, 783–84 (Fed. Cir. 2003) (affirming district court's denial of motion for reconsideration which presented evidence related to claim construction that party could have presented to the district court “during briefing or oral argument” (citations omitted, emphasis added)).

Moreover, the cases Vaxxinova cites in support of excluding the argument are distinguishable, in that they involve parties belatedly raising new terms for construction, *see Boehringer Ingelheim Pharma GmbH & Co. KG v. Teva Pharms. USA, Inc.*, 2017 U.S. Dist. LEXIS 235793, at *15–20 (D.N.J. Oct. 18, 2017) (affirming magistrate judge's decision to strike portion of expert report making claim construction argument where claim construction on other terms had already occurred and magistrate judge found defendants “willfully declined to raise their arguments . . . during the claim construction proceedings”), or moving to amend their invalidity

contentions with wholly new grounds for invalidity, *see Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC*, 2013 U.S. Dist. LEXIS 189253, at *13–16 (D.N.J Jan. 13, 2013) (rejecting request to amend invalidity contentions to add indefiniteness arguments defendant had known of but did not raise during claim construction); *Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, 2012 U.S. Dist. LEXIS 107408, at *23 (D.N.J. July 30, 2012) (rejecting motion to amend invalidity contentions to add new prior art where plaintiffs would have to engage in additional discovery, unduly prejudicing them). Here, Zoetis is advocating for the same construction of these terms it has all along, but simply adding “additional support for [a] previously argued claim construction” through reference to the patent prosecution history. *Inverness Med.*, 309 F.3d at 1381.

Alternatively, Vaxxinova argues the prosecution history presented by Zoetis does not constitute a “clear and unmistakable” disavowal of chelators other than 2,2-dipyridyl. (ECF No. 86 at 9.) Vaxxinova contends the applicants repeatedly challenged the patent examiner’s finding that Emery anticipated application claims 72, 81, and 82 and differentiated these claims from Emery for teaching “(1) a whole cell preparation of gram negative microbes comprising at least two siderophore receptor polypeptides (SRPs) and at least two porins and (2) a pharmaceutically acceptable carrier.” (*Id.* at 10.) In Vaxxinova’s reading of the amendments and prosecution history, they reflect the applicants’ frustration “with the examiner’s mischaracterization of the prior art and unwillingness to allow claims 72 and 81 even in the face of Vaxxinova’s arguments that the prior art clearly failed to anticipate claims 72 and 81,” rather than a desire to disclaim other chelators to overcome Emery. (*Id.* at 11.) Because they contend there is another reasonable interpretation of the amendments, Vaxxinova argues the amendments cannot amount to prosecution disclaimer. (*Id.* (citing *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016); *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1374 (Fed. Cir. 2022)).) Finally, Vaxxinova

accuses Zoetis of cherry-picking from the prosecution history by focusing on “[t]he cancelation of claims 72 and 81 and the amendments to claim 82,” to the exclusion of the other interactions between the applicants and examiner. (*Id.*)

The Federal Circuit provided an overview of the doctrine of prosecution history disclaimer in *Traxcell Techs., LLC v. Nokia Sols. & Networks Oy*, 15 F.4th 1136 (Fed. Cir. 2021):

“The doctrine of prosecution disclaimer . . . preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). “Prosecution disclaimer can arise from both claim amendments and arguments.” *SpeedTrack[, Inc. v. Amazon.com]*, 998 F.3d [1373,] 1379 [(Fed. Cir. 2021)] (quoting *Tech. Props. Ltd. v. Huawei Techs. Co.*, 849 F.3d 1349, 1357 (Fed. Cir. 2017)). And “[a]n applicant’s argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well.” *Id.* at 1380 (quoting *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007)). The doctrine “ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers.” *Id.* (cleaned up). It attaches if a patentee “has unequivocally disavowed a certain meaning to obtain [a] patent” in a way that is “clear and unmistakable.” *Omega*, 334 F.3d at 1324–26. If so, it “narrows the ordinary meaning of the claim congruent with the scope of the surrender.” *Id.*

Id. at 1141 (first, fifth, and sixth alterations in original). Under this doctrine, a patentee gives up everything clearly disclaimed, even if they could have overcome an examiner’s objection with a narrower disclaimer. See *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361–63 (Fed. Cir. 2005) (“[I]t frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art. In such cases, we have held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to.”).

The prosecution history makes clear the examiner repeatedly rejected numerous application claims, including 82, 85, 100, and 103, as anticipated by Emery in several respects, one of which was that “Emery et al discloses the use of metal chelators such as 2,2-dipyridyl.”

(ECF No. 79-1 at VAXX_000293; *id.* at VAXX_000202–03; *id.* at VAXX_000156.) In response to these repeated rejections based on Emery, the applicants ultimately cancelled multiple claims and significantly revised application claims 82, 85, 100, and 103 by combining them with application claims 81 and 99, respectively, and removing the general reference to “metal chelator” those claims had contained, resulting in the phrase “grown in the presence of 2,2-dipyridyl.” (ECF No. 79-1 at VAXX_000136.) While Vaxxinova points to the applicants’ statement of continued disagreement with the examiner’s view of anticipation by Emery accompanying the amendments as evidence of maintaining the scope to encompass all metal chelators (or at least iron chelators), (*id.* at VAXX_000145), this statement appears primarily directed at their decision to cancel many of the claims to which the examiner objected, not the amendments.⁴ The statement does not explain why removing the reference to “metal chelator” and replacing it with “2,2-dipyridyl” would preserve the scope of the former. *See, e.g., United Video Props., Inc. v. Amazon.com, Inc.*, 561 F. App’x 914, 918 (Fed. Cir. 2014) (affirming prosecution disclaimer where language similar to patentee’s proposed construction was removed via amendment, following rejection by examiner);

⁴ The applicants’ statements of respectful disagreement with the examiner and characterization of the amendments as “solely to expedite prosecution” (ECF No. 79-1 at VAXX_000145) do not negate disclaimer. *See Sandbox Logistics LLC v. Grit Energy Sols. LLC*, Civ. A. No. 3:16-12, 2018 WL 3344773, at *15 (S.D. Tex. July 9, 2018) *aff’d sub nom., SandBox Logistics LLC v. Proppant Express Invs. LLC*, 813 F. App’x 548 (Fed. Cir. 2020) (finding communications where examiner questioned support for aspect of patent claim and applicant replied “expressing ‘respectful[] disagree[ment]’ with that statement but nevertheless amending the claims to remove the . . . language” constituted disclaimer); *Split Pivot, Inc. v. Trek Bicycle Corp.*, 987 F. Supp. 2d 838, 874 n.18 (W.D. Wis. 2013), *aff’d*, 585 F. App’x 1011 (Fed. Cir. 2014) (“The fact that the remarks that accompanied the amendments state that they are made ‘[w]ithout acquiescing in the rejections or the grounds therefor, and solely to expedite prosecution’ does not change the court’s analysis. If overcoming prosecution history estoppel were as simple as including such boilerplate language with each amendment, the doctrine would be eviscerated.” (alteration in original) (internal citation omitted)); *Supernus Pharms., Inc. v. Torrent Pharms. Ltd.*, Civ. A. No. 21-06964, 2024 WL 1208663, at *33 (D.N.J. Jan. 30, 2024) (finding presumption of prosecution history estoppel where applicants amended claim but made remarks describing amendment as “solely in the interest of compact prosecution”).

Lemelson v. Gen. Mills, Inc., 968 F.2d 1202, 1298–1309 (Fed. Cir. 1992) (finding patentee disclaimed scope by canceling rejected claim and submitting amended version suggested by examiner). Nor does the fact the applicants provided several reasons to distinguish Emery in corresponding with the examiner prevent disclaimer of other chelators through amendment, as an applicant may disavow scope in one area while distinguishing a claim on other grounds as well. See *Traxcell Techs.*, 15 F.4th at 1141. And courts have noted that, in amending claims, patentees often disclaim more than necessary to avoid a prior art reference. See *Norian*, 432 F.3d at 1361–63 (finding disclaimer of solutions containing more than one sodium phosphate where patentee chose the phrase “a sodium phosphate” to avoid a prior art reference, rather than other formulations that would have been broader); *Julius Zorn, Inc. v. Medi Mfg., Inc.*, Civ. A. No. 3:15-02734, 2017 WL 960413, at *7–8 (S.D. Cal. Mar. 13, 2017) (finding term added by patent writer to differentiate claimed garment from prior art, “flat,” surrendered more than “only tubular garments”). Based on this prosecution history, as well as the indicia in the claims and specification, the Court concludes the applicants disclaimed metal chelators other than 2,2-dipyridyl.

Accordingly, the Court defines “expressed by the [a] gram negative microbe when the gram negative microbe is grown in the presence of [24 µg/mL] 2,2-dipyridyl” as “expressed by the [a] gram-negative microbe when the gram negative microbe is grown in the presence of [24 µg/mL] 2,2- dipyridyl.” The Court also defines “wherein at least one SRP is not expressed by the gram negative microbe at a detectable level when the gram negative microbe is grown in the absence of 2,2- dipyridyl” as “at least one of the at least two SRPs is characterized by being an SRP that is not present at a detectable level if the gram- negative microbe is grown in the absence of 2,2- dipyridyl.” The Court also defines “an SRP that is not expressed when the gram negative microbe is grown in the absence of 24 µg/mL 2,2-dipyridyl” as “an SRP is characterized by being an SRP

that is not present at a detectable level if the gram- negative microbe is grown in the absence of 24 µg/mL 2,2- dipyridyl.”

2. Indefiniteness

Because the Court has adopted Zoetis’s preferred construction of these terms, Zoetis asserts the Court should now find the terms are indefinite, and the claims are therefore invalid. (ECF No. 48 at 5–6 (citing *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004)).) Vaxxinova argues a finding of indefiniteness is inappropriate at this stage. (ECF No. 49 at 19–20; ECF No. 64 at 7–8.) Among other reasons, Vaxxinova contends: (1) Zoetis applied an overruled standard of indefiniteness, “insolubly ambiguous,” in making its argument (ECF No. 64 at 7–8); (2) the parties have not expressly agreed on who is a POSA for the ’048 Patent (*id.* at 8); and (3) Zoetis has not rebutted the opinion of Vaxxinova’s expert on these terms (as well as many others) (ECF No. 86 at 14).

To prove indefiniteness, a party must show by clear and convincing evidence that the asserted claims, viewed in light of the specification and prosecution history, fail to “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.* 572 U.S. 898, 899 (2014). “[T]he burden of proving indefiniteness remains on the party challenging validity and . . . they must establish it by clear and convincing evidence.” *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1227 (Fed. Cir. 2015). However, it is the typical practice of courts in this Circuit to defer consideration of an indefiniteness challenge until summary judgment or trial, when there is a fully developed expert record. See, e.g. *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, Civ. A. No. 17-9105, 2019 WL 2067373, at *10 (D.N.J. May 9, 2019) (“[T]his Court addresses invalidity disputes, of which indefiniteness is one, at summary judgment or at trial.”); *Adapt Pharma Operations Ltd. v. Teva Pharm. USA, Inc.*, Civ. A. No. 16-

7721, 2019 WL 1789463, at *4 (D.N.J. Apr. 24, 2019) (deferring decision on an indefiniteness challenge until the presentation of expert testimony); *Par Pharm., Inc. v. Sandoz, Inc.*, Civ. A. No. 18-14895, 2020 WL 1130387, at *8 (D.N.J. Mar. 9, 2020) (same).

As Vaxxinova argues, and the Court agrees, the factual record is not fully developed, in particular with regard to expert testimony. Therefore, this Court declines to rule the claim terms as construed are invalid at this stage. *See Adapt Pharma*, 2019 WL 1789463, at *4.

B. The Meaning of “wherein the gram negative microbe comprises an E. coli mutant lacking outer oligosaccharide side chains of LPS”

Claim Language	Asserted Claims	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
“wherein the gram negative microbe comprises an <i>E. coli</i> mutant lacking outer oligosaccharide side chains of LPS”	Claim 21; Claim 22	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiff proposes the following: “the gram-negative microbe includes a mutant or modified strain of <i>E. coli</i> bacteria having lipopolysaccharides that lack outer oligosaccharide side chains.”	The term is indefinite and is not reasonably amenable to a construction at least because the bounds of this term cannot be defined.

Claims 21 and 22 in the ’048 Patent teach compositions containing gram negative microbes under certain conditions. ’048 Pat. at col. 41 l. 48 – col. 42 l. 4. Claim 21 is rewritten in full as an exemplar:

21. A composition comprising:
an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise:
at least two siderophore receptor polypeptides (SRPs);
and
at least two porins; and
a pharmaceutically acceptable carrier;
wherein the gram negative microbe comprises an *E. coli* mutant lacking outer oligosaccharide side chains of LPS.

Id. at col. 41 ll. 48–58.

Vaxxinova argues no construction of the phrase “wherein the gram negative microbe comprises an *E. coli* mutant lacking outer oligosaccharide side chains of LPS” is required because a POSA would understand “the lack of outer oligosaccharide side chains refers to the *E. coli* strain’s LPS compositional structure” (ECF No. 49 at 31), denoting that the microbe’s LPS have “absent or reduced oligosaccharide side chains of LPS” (*id.* at 32). Zoetis argues Vaxxinova’s description of O-chains of LPS belies the “inherent variability” of the number of side chains of LPS in *E. coli*, “even within one culture,” such that a POSA could not tell “whether any given culture fell within the bounds of this limitation.” (ECF No. 48 at 22.) As a result, Zoetis contends this term is indefinite and these claims are invalid. (*Id.* at 21.) In response, Vaxxinova reiterates its arguments that the Court should not consider the question of invalidity at this time.

Based on the parties’ arguments, including their presentations at oral argument, and the conflicting declarations and depositions of their experts, the Court is not convinced by Vaxxinova’s argument for plain and ordinary meaning or its alternative definition, as the parties dispute the ability of a POSA to reasonably ascertain the number of oligosaccharide side chains of LPS under a variety of conditions. Consistent with the approach above, this Court declines to rule on Zoetis’s invalidity argument at this time and defers its decision on this issue until a more complete record is developed. *See Adapt Pharma*, 2019 WL 1789463, at *4.

C. The Meaning of “[at least two/a plurality of] [siderophore receptor polypeptides (SRPs)/porins]”

Claim Language	Asserted Claims	Plaintiff's Proposed Construction	Defendant's Proposed Construction
“at least two siderophore receptor polypeptides (SRPs)”	Claim 4; Claim 6; Claim 21	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiffs propose the following: “two or more types of siderophore receptor polypeptides.”	The term is indefinite and not amenable to construction. Whether “at least two” refers to two molecules, or two different kinds, of siderophore receptor polypeptide is indefinite and no definition finds support in the patent claims, specification, or prosecution history.
“at least two porins”	Claim 4; Claim 6; Claim 21	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiffs propose the following: “two or more types of porin polypeptides.” While porins are understood by persons of ordinary skill in the art and do not need any construction, to the extent any construction is deemed necessary, porins are trans-membranous pore-forming proteins in the outer membrane of Gram-negative bacteria through which small molecules can diffuse.	The term is indefinite and not reasonably susceptible to a definition. Whether this limitation requires at least two porin molecules or two types of porin is undefined.
“a plurality of siderophore receptor polypeptides (SRPs)”	Claim 14; Claim 16; Claim 22	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiffs propose the following: “two	The claim term is indefinite and not reasonably amenable to definition. The plain meaning of plurality is two or more. However,

		or more types of siderophore receptor polypeptides.”	whether “a plurality” refers to two or more molecules, or two or more different kinds, of siderophore receptor polypeptide is undefined.
“a plurality of porins expressed by the [a] gram negative microbe”	Claim 14; Claim 16; Claim 22	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiffs propose the following: “two or more types of porin proteins expressed by the respective Gram-negative bacteria under the stated conditions.”	The claim term is indefinite and not reasonably amenable to definition. The plain meaning of plurality is two or more. However, whether “a plurality” refers to two or more molecules, or two or more different kinds, of siderophore receptor polypeptide is undefined.

Zoetis contends claim terms containing “at least two” or “a plurality of” SRPs or porins are indefinite and not amenable to construction because they do not reasonably inform a POSA of the scope of the relevant claims, i.e., whether these phrases refer to two molecules or two different kinds of the SRP or porin. (ECF No. 48 at 27.) Zoetis contends there is no intrinsic evidence supporting Vaxxinova’s construction, and an article Vaxxinova points to as extrinsic evidence postdates the ’048 Patent application, meaning it should not be considered. (*Id.*)

Vaxxinova argues these terms need no construction, as POSAs “with knowledge of molecular biology, microbiology, or a related field simply do not work at a molecule-by-molecule level when working on cell preparations or vaccines.” (ECF No. 64 at 25.) Because the inventions taught by the ’048 Patent relate to the commonality of SRP receptors across different species of microbes, a POSA would understand the terms “at least two” or “a plurality of” to refer to two or

more types of polypeptides. (ECF No. 49 at 18.) Vaxxinova also asserts the specification continually references compositions of “two or more types of SRPs from one or more genera or one or more species of microbes, identifying as examples that certain species of *Salmonella* produce three SRPs and *E. coli* have been found to produce as many as six SRPs.” (*Id.* (citing ’048 Pat. at col. 6 ll. 14–50; at col. 5 l. 64 – col. 6 l. 13; col. 5 ll. 23–25).) Further, Vaxxinova cites the declaration of Dr. Galen to assert it would be “nonsensical” to a POSA to discuss individual molecules in a vaccine preparation, or any industry application, because “molecules are counted on exponential scales.” (*Id.* at 19.) In response, Zoetis argues Vaxxinova is wrong because “(1) the claims do not recite a vaccine, and (2) . . . the number of [whole cells of gram negative microbes] is not defined in the claims. Vaxxinova does not contend that it would be preposterous to discuss at least two molecules of SRP per gram negative microbe.” (ECF No. 62 at 30–31.)

The Court agrees with Vaxxinova that no construction is necessary, as the plain and ordinary meaning would be apparent to a POSA. In particular, the specification’s description of the SRPs produced by different species of *Salmonella* supports Vaxxinova’s contention: “Typically, different species of *Salmonella* each produce three SRPs. Without intending to be limited by theory, it is believed that the three SRPs produced by *Salmonella* spp. are receptors for the siderophores enterochelin, aerobactin, and ferrichrome.” ’048 Pat. at col. 6 ll. 29–33. It is clear from this language the patentees are talking about *types* of SRPs, not three molecules of an SRP, as the phrase “three SRPs” corresponds with the three different types of siderophores listed, “enterochelin, aerobactin, and ferrichrome.” *Id.*; *see also Vitronics*, 90 F.3d at 1582 (“The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”). While this implicit definition in the specification is sufficient to demonstrate Zoetis’s indefiniteness argument is wrong, Dr. Galen’s unrebutted statement on what

a POSA would understand these terms to mean buttresses the Court's view a construction is not necessary. *See, e.g., Vifor (Int'l) AG v. Mylan Lab'ys Ltd.*, Civ. A. No. 19-13955, 2021 WL 2652123, at *5 (D.N.J. June 28, 2021) (looking to unrebutted expert testimony in claim construction); *Honeywell Int'l, Inc. v. United States*, 609 F.3d 1292, 1299 (Fed. Cir. 2010) (same).

Accordingly, the Court finds “[at least two/a plurality of] [siderophore receptor polypeptides (SRPs)/porins]” is entitled to its plain and ordinary meaning and requires no construction.

D. The Meaning of “A composition comprising: an isolated whole cell preparation [of gram negative microbes]”

Claim Language	Asserted Claims	Plaintiff's Proposed Construction	Defendant's Proposed Construction
“A composition comprising: an isolated whole cell preparation [of gram negative microbes]”	Claim 4; Claim 6; Claim 21	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiffs propose the following: “a composition containing, but not limited to, whole cells or cell debris isolated from a Gram-negative bacteria.”	“A composition comprising whole microbial cells where the whole cells have been removed from their natural environment.”

Vaxxinova argues the term “a composition comprising: an isolated whole cell preparation [of gram negative microbes]” requires no construction because a POSA would readily understand its scope and meaning, and Zoetis has provided no reason to deviate from what a POSA would customarily understand. (ECF No. 49 at 14 (citing *Vitronics*, 90 F.3d at 1582).) Zoetis proposes the Court should construe this term as “a composition comprising whole microbial cells where the whole cells have been removed from their natural environment.” (ECF No. 48 at 34.)

Because the phrase “a composition comprising” is a preamble and provides no limitation to the claim, Vaxxinova contends it does not need to be construed. (ECF No. 49 at 14–15 (citing

Pitney Bowes, 182 F.3d at 1305; *Symantec Corp. v. Comput. Assocs. Int'l, Inc.*, 522 F.3d 1279, 1288–89 (Fed. Cir. 2008)).) Vaxxinova also points out that Zoetis agrees the terms “composition” and “whole cell” should take their plain and ordinary meaning, so the only word within the claim term at issue is “isolated.” (*Id.* at 15.) However, Vaxxinova asserts Zoetis does not proffer a basis “to give this term anything but its plain and ordinary meaning.” (*Id.*)

In the alternative, Vaxxinova argues the Court should construe this term as “a composition containing, but not limited to, whole cells or cell debris isolated from a Gram-negative bacteria,” consistent with a POSA’s customary understanding. (*Id.*) Vaxxinova points to the Manual of Patent Examining Procedure (“MPEP”) to assert “comprising” means “containing, but not limited to.” (*Id.* at 15–16 (citing MPEP § 2111.03).) Vaxxinova also contends its construction, which would allow for a composition containing “whole cells or fragments of whole cells,” is consistent with the ’048 Patent specification’s discussion of whole cell preparations and the file history’s prior art distinction between isolated whole cells and isolated polypeptides. (*Id.* at 16 (citing ’048 Pat. at col. 15 ll. 6–30, Examples 6 & 7; Declaration of Christopher R. Kinkade, Esq. dated April 23, 2024 at ¶ 3 Ex. 1).)

Zoetis agrees the construction of this term turns on the meaning of “isolated” but argues there is nothing in the ’048 Patent to support Vaxxinova’s interpretation. (ECF No. 48 at 35.) Zoetis argues Vaxxinova’s construction would allow for a composition that includes only cell debris “instead of whole cells,” and such a reading is not supported by the ’048 Patent’s description. (*Id.*) Zoetis also contends the use of the phrase “whole cell preparation” in the term by itself necessitates “the presence of whole cells in the preparation, not just cell debris.” (*Id.*) Zoetis asserts Vaxxinova’s proposed construction would deny any meaning to the term “isolated” within the claims, and points to three instances within the ’048 Patent where the inventors provided

a definition of “isolated” in the context of polypeptides and describes them as “removed from their natural environment.” (*Id.* at 36–37 (citing ’048 Pat. at col. 4 ll. 23–24, at col. 20 ll. 40–41, at col. 25 ll. 23–24, at col. 38 ll. 41–43).) Further, Zoetis argues the ’048 Patent is devoid of any descriptions of “making bacterial cells synthetically or by recombinant techniques,” indicating the bacteria must be removed from their natural environment. (*Id.* at 37.) Additionally, Zoetis refutes that the portion of the prosecution history Vaxxinova cites supports its construction, as the discussion between the examiner and the applicants does not reference cell debris, only whole cells. (ECF No. 62 at 34 (citing Ex. O).)

In reply, Vaxxinova contests that the intrinsic record demonstrates the term “isolated” must mean “removed from their natural environment.” While the references Zoetis makes to the ’048 Patent discuss removing bacteria from animal hosts, Vaxxinova argues the claims themselves do not specify the claimed composition needs to originate in an animal host, as opposed to a bacterial colony maintained for research purposes, such as by ATCC. (ECF No. 64 at 27–28.) Vaxxinova also refers to the Merriam Webster definition of “isolated”⁵ to argue in support of their view that “[a]pplied here, “isolated” refers to purification” from other agents. (*Id.* at 28.)

Looking to the ’048 Patent and its prosecution history, the Court finds no reference to “cell debris” or “cell fragments”; indeed, the portions of the specification and file history Vaxxinova cites reference only “whole cells.” Vaxxinova cites the description of a “whole cell preparation” in the ’048 Patent that can be made from modified or mutant *E. coli*. ’048 Pat. at col. 15, ll. 6–30. But this example explicitly states that “to enhance the immune stimulating capability of an immunizing composition *made with intact bacterial cells* to elicit an anti-SRP immune response,

⁵ “To select from among others, especially: to separate from another substance so as to obtain pure or in a free state.’ <https://www.merriam-webster.com/dictionary/isolate> (last visited June 14, 2024).” (ECF No. 64 at 28.)

the cell membrane can be chemically altered . . . or a mutant organism . . . can be used.” *Id.* (emphasis added). And the preparations of isolated bacteria Vaxxinova points to in Examples 6 and 7 of the ’048 Patent specification either discuss whole cells explicitly or do not characterize the cells at issue. *Id.* at col. 27 ll. 56–60 (“All suspect isolates were confirmed to be *Salmonella* using *Salmonella* O antiserum . . . Briefly, a colony is removed from a plate and mixed in a drop of poly O antiserum. This is mixed for about 30 seconds if it agglutinates it’s a confirmed suspect.”); at col. 28 ll. 40–43 (“The hyperimmune and control sera was absorbed with killed *whole cell bacteria* of *Salmo-nella bredeney* grown in iron-replete media (BHI containing 200 um ferric chloride) for 1 hour at 4° C.”) (emphasis added).

Similarly, the sections of the prosecution history Vaxxinova cites undercut its assertion that the claimed composition may include cell debris alone. In responding to the examiner’s rejection of application claims based on Emery, discussed *supra*, the applicants distinguished the claims from the prior art involving isolated SRPs and porins because “Emery fails to disclose, and the Office Action fails to assert that Emery discloses, a vaccine that *includes whole cells* combined with a pharmaceutically acceptable carrier.” (ECF No. 79-1 at VAXX_000254 (emphasis added).) By using the word “includes,” the applicants clearly characterize whole cells as a necessary element to the invention described in the ’048 Patent.

It does not follow, however, that Zoetis is correct in its reading that the whole cells must be removed from their natural environment to be “isolated” as described in the term. While Zoetis points to several examples from the specification where the ’048 Patent discusses obtaining “isolated” polypeptides from a natural environment, i.e., an animal host, ’048 Pat. at col. 4 ll. 23–24, at col. 20 ll. 40–41, at col. 25 ll. 23–24, at col. 38 ll. 41–43, the Court does not read these passages as defining “isolated” in such a limited manner. In fact, the first of these specification

excerpts states: “An ‘isolated’ polypeptide means a polypeptide that has been *either* removed from its natural environment, *produced using recombinant techniques, or chemically or enzymatically synthesized.*” (*Id.* at col.4 ll.23–26 (emphasis added).) Through this description, it appears the patentees defined “isolated” to encompass both natural and synthetic means for obtaining a desired product. *See Phillips*, 415 F.3d at 1316.

Accordingly, the Court defines “a composition comprising: an isolated whole cell preparation [of gram negative microbes]” as “a composition comprising whole microbial cells where the whole cells have been either removed from their natural environment, produced using recombinant techniques, or chemically or enzymatically synthesized.”

E. The Meaning of “Detectable level”

Claim Language	Asserted Claims	Plaintiff’s Proposed Construction	Defendant’s Proposed Construction
“Detectable level”	Claim 6; Claim 7; Claim 16; Claim 17	Plain and ordinary meaning. If a construction other than plain and ordinary meaning is required, then Plaintiffs propose the following: “the amount of a protein that can be identified using a given assay (e.g., polyacrylamide gel analysis using conventional Coomassie staining, western immunoblotting analysis using primary antibodies capable of binding to the protein of interest, [or mass spectrometry technologies] ⁶).”	This term is indefinite and cannot reasonably be construed.

⁶ The bracketed language is included in Vaxxinova’s proposed construction in Exhibit A of the prehearing statement (ECF No. 45), but it is not included in Vaxxinova’s briefings.

Claim 6 of the '048 Patent is representative of how the disputed term “detectable level” is used:

6. A composition comprising:
an isolated whole cell preparation of gram negative microbes,
wherein the gram negative microbes comprise:
 - at least two siderophore receptor polypeptides (SRPs),
wherein at least one SRP is not expressed by the
gram negative microbe at a detectable level when the
gram negative microbe is grown in the absence of
2,2-dipyridyl; and
 - at least two porins; anda pharmaceutically acceptable carrier.

Vaxxinova argues no construction is necessary for “detectable level” because a POSA would understand “how to run an assay to detect the presence of a specific protein.” (ECF No. 49 at 27.) Because the '048 Patent discusses established techniques for identifying proteins—“SDS-PAGE,” “Western Immunoblot,” and “ELISA”—Vaxxinova asserts it is unnecessary for the claims to provide further direction to a POSA on well-known methodologies. (*Id.* at 28 (citing *Streck, Inc. v. Rsch. & Diagnostic Sys.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); ECF No. 64 at 13.) Vaxxinova also contends Dr. Galen and Zoetis’s expert, Dr. Trevor Ames, agree it is “common” for a POSA to continually refine and optimize their detection methodologies based on a variety of factors, including the experiment’s goals and the POSA’s experience, and to start with SDS-PAGE, with Western Immunoblot and ELISA serving as “complements.” (ECF No. 64 at 14–15, 17.)

Zoetis contends “detectable level” is impermissibly indefinite because it fails to identify a single method of detection for the proteins at issue, despite the varying limits of detection among common methods. (ECF No. 48 at 38–39.) While Zoetis acknowledges a POSA would be aware of common methods of detection, it argues “there are many different possible ways to perform those methods,” and the '048 Patent provides only a broad, general description of them, “meaning

a [POSA] could not reproduce the methodology.” (*Id.*) Zoetis also argues Dr. Galen admitted on cross-examination the detection methodologies listed in the ’048 Patent specifications could lead to different results based on their differing levels of sensitivity, limitations that could be exacerbated by differences among reagents, equipment, and methodology between laboratories. (ECF No. 62 at 36–38.) Zoetis cites *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344–45 (Fed. Cir. 2015), to support the idea that, where multiple measurement methods exist, a patent claim is indefinite if it does not provide reasonable certainty about the invention’s scope by indicating which method is used. (ECF No. 48 at 39.)

In response, Vaxxinova says *Teva Pharms.*, Zoetis’s primary legal authority, is distinguishable because there, the challenger showed competing existing methodologies reached different results, and the patent did not provide instruction on which to use, whereas here, Dr. Ames confirmed an understood order of assays among POSAs, with SDS-PAGE as the primary assay to detect proteins, and the other tests as complements. (ECF No. 64 at 15.) Vaxxinova points to *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1376 (Fed. Cir. 2017), which found a patent not to be indefinite where it used a measurement technique not discussed in detail in the patent or peer-reviewed literature, but that a POSA could easily ascertain from the general description and their own knowledge of the art. (*Id.* at 16.)

The Court finds that the term “detectable level” does not require construction. The ’048 Patent refers to the SDS-PAGE, Western Immunoblot, and ELISA techniques in a general manner, and the parties’ experts agree these approaches are well-known in the art.

Vaxxinova’s citation to *Presidio Components* is instructive here. In *Presidio Components*, the patent for a multilayer capacitor included “fringe-effect capacitance between external contacts that is ‘capable of being determined by measurement in terms of a standard unit.’” 875 F.3d at

1375 (quoting patent). The specifications referenced a method for measuring capacitance that was well-known in the art but did not describe the steps in detail, and the method’s use on multilayer capacitors had not been well-known at the time. *Id.* at 1376. But at trial, Presidio’s expert explained a POSA would know how to take this well-known method and apply it to a multilayer capacitor based on their knowledge of the art, resulting in standard unit measurements. *Id.* The Federal Circuit concluded this was sufficiently definite to inform skilled artisans. *Id.*

“To be sure, even where the claims require a particular test result, there may be (and often are) disputes between the parties as to the proper application of the test methodology in the circumstances of an individual case. *But those disputes are disputes about whether there is infringement, not disputes about whether the patent claims are indefinite.* Here, the general approach was sufficiently well established in the art and referenced in the patent to render the claims not indefinite.”

Id. at 1377 (emphasis added).

While, in accordance with Third Circuit practice, this Court reserves indefiniteness arguments for summary judgment, the Federal Circuit’s reasoning applies equally to determining no construction is necessary. The experts on both sides agree a POSA would be familiar with all the techniques described in the ’048 Patent for detecting proteins and would also be well-versed in the iterative process of running SDS-PAGE and adjusting its parameters and/or employing Western Immunoblot and ELISA as necessary. (ECF No. 64 at 14–15, 17.) A POSA could therefore employ a known method to determine the presence of a “detectable level” of the relevant protein, and any dispute would turn on “the proper application of the test methodology in the circumstances of an individual case.” *Presidio Components*, 875 F.3d at 1377. As there is no contrary intrinsic evidence, this agreement between experts is sufficient at this stage to show a POSA would be able to read and understand the term “detectable level” as used in the ’048 Patent.

Accordingly, the Court finds “detectable level” is entitled to its plain and ordinary meaning

and requires no construction.

IV. CONCLUSION

For the reasons set forth above, this Court defines the disputed claim terms as defined above. An appropriate order follows.

Date: January 23, 2025

/s/ Brian R. Martinotti

**HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE**